Canadian Patent Infringement Exceptions

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Recent Canadian court cases have provided insight into the scope of statutory "safe harbour" exemptions from patent infringement. The safe harbour in s. 55.2(1) of the Canadian *Patent Act* provides a patent infringement exemption for activities reasonably related to generation of information for a regulatory agency, such as Health Canada or the U.S. FDA. The Canadian safe harbour is based on a similar provision in U.S. law, except the Canadian law is broader in that it is not limited to drug development but could apply to other types of regulatory approvals. There are also common law exceptions to patent infringement which are created in court decisions, not statutes passed by the government. The common law exception is narrow, for example permitting testing of an invention merely to see if it works. The narrow scope of this common law exemption was part of the reason for enacting the broader safe harbor.

Most of the recent court decisions were in the pharmaceutical industry. A leading Canadian decision, *Merck et al. v. Apotex* ([2006] FCA 323, Federal Court of Appeal), was made in the context of *generic* drug development. In the *Merck* case, the Canadian Court held that Apotex prepared and tested the patented lisinopril drug for the purposes of filing abbreviated new drug submissions necessary to sell lisinopril in Canada and the United States. Not all lisinopril data was referenced in Apotex's submissions, but all data was directed to that purpose. Apotex also had stored samples in the event that they were required for future reference by the government. The Court concluded that section 55.2(1) was sufficiently broad to exempt these generic drug development activities from infringement. The safe-harbour can protect activities reasonably related to development and submission of information required by law, either before or after market approval. The Court also found that Apotex's use of lisinopril in ongoing research and development of alternate formulations and alternate techniques for tablet-making fell within the *common law* exemption to infringement. This was because they did not proceed beyond an experimental (testing) phase and did not take steps to manufacture, promote and sell the product.

The safe harbour may not apply if the drug samples used for regulatory purposes are commercialized subsequent to their use for regulatory purposes. In *Apotex Inc. v. Sanofi-Aventis*, 2013 FCA 186, since the generic company could not produce records showing the destruction of the disputed lots of drug clopidogrel, it was concluded that it had not demonstrated that the experimental and regulatory use exemption applied to those lots. Therefore, as a best practice, unused drug originally obtained for regulatory purposes should later be either producible or destroyed in a documented manner. This better practice was shown in a subsequent case, *Teva Canada Ltd. and Apotex v. Novartis* AG, 2013 FC 141. Apotex had carefully prepared evidence to account for all its test imatinib, and provided an undertaking to the Court that whatever is left over after the regulatory process is completed will be destroyed. In that case, the leftover material was not covered by the safe harbour, but could nonetheless be retained subject to the undertaking that it will be destroyed after reaching its expiry date.

There has not yet been a Canadian case in the context of innovative drug development (competing innovative companies), or use of a patented research tool, so there is still some uncertainty as to how the safe harbor applies in those situations. The safe harbor should have some applicability to the innovative drug development context because it was recently considered to be potentially available in the context of a mechanical device case involving two competitors developing helicopter landing gear (*Eurocopter v. Bell Helicopter Textron Canada Ltée*, 2012 FC 113, aff'd 2013 FCA 219). However, Bell's argument failed because there was evidence that its landing gears were used for commercial purposes in addition to regulatory testing. The activities were therefore not solely for uses reasonably related to the development and submission of information required by law.

The Canadian safe harbour provides a useful tool for companies intending to do development for regulatory-related purposes in Canada. The boundaries of the infringement exception must be kept in mind, since any non-regulatory development, or change in character to commercial use risks infringement.

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